

State of North Carolina

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North Carolina Senate President Pro Tempore Marc Basnight North Carolina House of Representatives Speaker Joe Hackney Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator John Snow
Senator Ellie Kinnaird
Representative Alice Bordsen
Representative Jimmy Love
Co-Chairs, Appropriations Subcommittees on Justice and Public Safety

North Carolina General Assembly Raleigh, North Carolina 27601-1096

RE: G.S. §114-2.5; Report on Settlement Agreement for Medicis Pharmaceutical Corporation

Dear Members:

G.S. §114-2.5 requires the Attorney General to report to the Joint Legislative Commission on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than \$75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the State and Federal governments in the above-referenced matter. Pursuant to federal law (42 CRS 433.320) recoveries in these cases are shared on a pro-rata basis by the State and Federal governments.

Medicis Pharmaceutical Corporation (Medicis) is a company located in Scottsdale, Arizonia, which engages in the manufacture, marketing, and distribution of pharmaceutical products. Medicis entered into civil agreements with 48 states and the District of Columbia and the federal government in which Medicis agreed to pay \$9.8 million to resolve allegations that the company promoted the use of a topical skin preparation, Loprox, for use on children under the age of 10, without approval by the Food & Drug Administration (FDA). The settlement also resolves claims brought by four former Medicis sales representatives in the Federal District Court of Kansas. The participating states and the federal government alleged that from

approximately November, 2001 through April, 2004, sales representatives at Medicis targeted pediatricians, urging the doctors to use Loprox as a treatment for diaper rash. The use of Loprox, which is approved by FDA as a fungicide for patients over 10 years of age, is not a "medically accepted indication" for the treatment of diaper dermatitis and other skin disorders in children under 10 years of age. As a result of this "off-label" promotion by Medicis, state Medicaid programs paid for Loprox prescriptions that would not have been reimbursed if government authorities had known that the prescriptions resulted from such a marketing campaign.

Under the terms of North Carolina's settlement, North Carolina will recover \$687,825.11. Of that amount \$147,825.10 will be paid directly to the North Carolina Medicaid Program for the states share of the monies recovered. A portion of the state share will be returned to the affected counties based upon their financial participation in the Medicaid Program. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. §115C-457.1, the penalty portion of the settlement in the amount of \$135,332.55 will be paid to the Civil Penalty Forfeiture Fund for the support of the public schools. Pursuant to G.S. §115C-457.2, the North Carolina Department of Justice will receive \$2,705.55 for costs of collection. The balance will go to the federal government to reimburse its share of the Medicaid costs.

As part of the settlement, Medicis entered into a Corporate Integrity Agreement with the United States Department of Health and Human Services' Inspector General. The agreement includes provisions that Medicis will implement an internal Code of Conduct to ensure that it will market, sell, promote, research, develop and advertise its products in accordance with all Federal health care program and FDA requirements.

We will be happy to respond to any questions you may have regarding this report.

Very truly yours,

Kristi Hyman Chief of Staff

KH:kds

cc: Jean Sandaire, NCGA Fiscal Research Division Greg McLeod, NCDOJ, Legislative Counsel Nels Roseland, NCDOJ, Deputy Chief of Staff